

IN THE SUPERIOR COURT OF THE STATE OF DELAWARE

**DAWNETTE BREDBERG
AND MICHAEL BREDBERG**

Plaintiffs,

v.

**Boston Scientific Corporation
(D/B/A Mansfield Scientific, Inc.)
And Microvasive, Inc.,**

Defendants.

C.A. No.: N20C-10-031 PEL

Submitted: June 16, 2021

Decided: July 2, 2021

**ON PLAINTIFF'S MOTION TO FOR REARGUMENT –
MOTION DENIED**

ORDER

*Robert J. Leoni, Esquire, Shelby & Leoni, 221 Main Street Wilmington, DE 19804,
Attorneys for Plaintiff.*

*Colleen Shields, Esquire and Alexandra D. Rogin, Esquire Eckert, Seamans, Cherin
& Mellott LLC, 222 Delaware Ave., 7th Floor, Wilmington, DE 19801, Attorneys for
Defendant*

Jones, J.

Plaintiffs Dawnette and Michael Bredberg (the “Bredbergs”) have filed a Motion for Reargument (the “Motion” or “Rule 59 Motion”) in this case. The Bredbergs contend that this Court misapprehended the pertinent facts and Delaware law when the Court granted a Motion to Dismiss the claims in this litigation by Defendant Boston Scientific Corporation (“Boston Scientific”) in an Opinion and Order issued on June 2, 2021. The Plaintiffs now request that the Court reverse its Order granting Boston Scientific’s Motion to Dismiss under Superior Court Rule of Civil Procedure 59(e).

The Court is not persuaded that it misapprehended the key facts relevant to the Motion to Dismiss or that it misapplied the law. For the reasons explained below, the Bredbergs’ Motion for Reargument will be **DENIED**.

FACTUAL AND PROCEDURAL BACKGROUND

In April of 2005, Dawnette Bredberg underwent surgery to implant her with a pelvic mesh device manufactured by Boston Scientific called the Obtryx. The Obtryx is a pelvic mesh device intended to treat stress urinary incontinence and other related medical issues which arise from damage or weakening of the walls of the vagina. Dawnette claimed to have suffered “serious bodily injuries, including but not limited to erosion and other injuries” as a result of her Obtryx implantation, and also claimed that “as a result of having the [Obtryx] implanted into her, Dawnette [] has experienced significant mental and physical pain and suffering, and has

sustained permanent injury.”¹ Dawnette experienced medical complications following her Obtryx implantation surgery and underwent revision surgeries to remove mesh from the Obtryx which had eroded inside of her body in December of 2005 and October of 2018.

On October 2, 2020, Plaintiffs filed the initial Complaint in this action. The Complaint named Boston Scientific as the sole defendant in this action, and brought direct claims by Dawnette against Boston Scientific for Negligence (Count I), Breach of Warranty (Count II), and Failure to Warn (Count III). The Complaint also contained a derivative claim by Dawnette’s husband, Michael Bredberg, for Loss of Consortium (Count IV). The text of the Complaint did not list the dates of Dawnette’s revision surgeries in December of 2005 and October of 2018.

Boston Scientific filed a Motion to Dismiss the action on November 23, 2020. In response to Boston Scientific’s Motion to Dismiss, the Bredbergs filed a Response Brief. The Bredbergs’ Response Brief listed the dates of both of Dawnette’s revision surgeries, which took place in December of 2005 and October of 2018.² The Response Brief also attached a Plaintiff Profile Form as an exhibit.³ This Profile Form also listed the dates of Dawnette’s revision surgeries. After full briefing on the motion to dismiss, this Court issued an Opinion and Order on June 2, 2021 (the

¹ Compl. ¶¶ 48, 50.

² Pl.’s Response to Def.’s Mot. To Dismiss (hereinafter, “Response”), at 1 (“On December 28, 2005, Mrs. Bredberg underwent revision surgery to remove mesh from the Obtryx device that eroded into her vagina. . . On October 3, 2018, Mrs. Bredberg underwent a second revision surgery to partially excise the mesh from her body.”).

³ Ex. B to Response (hereinafter “Plaintiff Profile Form.”)

“Opinion”). The Opinion granted the Defendant’s Motion to Dismiss the action in full. The Plaintiffs’ personal injury claims contained in Counts I & III and the derivative Loss of Consortium claim contained in Count IV were dismissed on the basis that the statute of limitations for these actions had expired. Specifically, the Opinion stated:

Defendant argues that Dawnette Bredberg’s personal injury claims accrued in either December of 2005 following her first revision surgery or October 2008 following a public notice of defects associated with pelvic mesh devices issues by the Food & Drug Administration. *In either case*, the statute of limitations for Plaintiffs’ personal injury claims would have expired long before Plaintiffs filed the instant lawsuit on October 2, 2020. . . In the instant case, Plaintiff had a second mesh revision surgery in December of 2005. In 2008 the FDA issued a notice that there was a connection between the type of symptoms Plaintiff suffered and pelvic mesh implants. These two facts lead this Court to conclude that by 2008, Plaintiff’s claims had accrued, and the statute of limitations had started to run. This means that the statute of limitations expired two years later in 2010 *at the latest*. The Complaint in this action was not filed until 2020, and by this time the products liability claims were time-barred.⁴

On June 9, 2021, the Bredbergs filed the instant Motion for Reargument. The Motion for Reargument seeks reversal of this Court’s Opinion granting the Motion to Dismiss with respect to the personal injury claims contained in Counts I and III of their Complaint and the derivative loss of consortium claim contained in Count IV.⁵

⁴ *Bredberg v. Boston Scientific*, at 6,8 (Del. Supr. June 2, 2021)(emphasis added.)

⁵ Plaintiffs’ instant Motion does not seek reargument on the Breach of Warranty claim contained in Count II of the original Complaint. The Breach of Warranty Count was dismissed pursuant to a different statute of limitations standard than Plaintiffs’ other claims. This Order will not address that Count.

Boston Scientific filed a Reply Brief on the instant Motion for Reargument on June 21, 2021. The matter has been fully briefed and is ripe for decision.

STANDARD OF REVIEW

A motion for reargument under Rule 59(e) gives a trial court an opportunity to reconsider its findings of fact, conclusions of law, and ultimate judgment on a decision.⁶ Motions for reargument are governed by the framework of Superior Court Rule of Civil Procedure 59. “Delaware law places a heavy burden on a [party] seeking relief pursuant to Rule 59.”⁷ On a motion for reargument, the moving party bears the burden of demonstrating that the Court must correct an error of law, a misapprehension of fact, or must alter its judgment in order to prevent manifest injustice occasioned by its decision.⁸ This is not an easy standard to meet. The grounds upon which a party may successfully make a motion for reargument are narrow: “A Rule 59(e) application [for a motion for reargument] is not an avenue for the moving party to raise new arguments or to rehash arguments already decided by the Court.”⁹ A motion for reargument will be denied unless the Court’s previous ruling “overlooked a controlling precedent or legal principles” or “has misapprehended the law or facts” in a way that would change the ultimate outcome

⁶ See *Ramon v. Ramon*, 963 A.2d 128, 136 (Del. 2008) (citing substantively identical Family Court Civil Procedure Rule 59(e)).

⁷ *Newborn v. Christiana Psychiatric Services, P.A.*, 2017 WL 394096, at *2 (Del. Supr. 2017) (internal citations omitted.)

⁸ See e.g. *Paron Capital Management v. Crombie*, 2012 WL 3206410, at *1 (Del. Ch. Aug. 2, 2012)(internal citations omitted).

⁹ *Maravilla-Diego v. MBM Construction II, LLC*, 2015 WL 5055955, at *1 (Del. Supr. 2015).

of the challenged decision.”¹⁰ In a motion for reargument under Rule 59(e), the Court “will determine from the motion and answer whether the reargument will be granted.”¹¹

Plaintiff’s instant Motion for Reargument fails to meet this demanding standard, and will be **DENIED** in full.

ANALYSIS

This Court granted Boston Scientific’s Motion to Dismiss on grounds that the statute of limitations for Dawnette Bredberg’s direct personal injury claims and Michael Bredberg’s derivative loss of consortium claim had expired before the Bredbergs filed their Complaint in this action. The core argument contained in Plaintiff’s Rule 59 Motion is that the Court improperly considered the December 2005 date of Dawnette’s first revision surgery and a 2008 FDA Notice detailing defects associated with pelvic mesh products like the Obtryx in granting Boston Scientific’s dismissal motion. Plaintiffs’ Rule 59 Motion claims that the Court “misapprehended the factual bases of Plaintiffs’ claim to include the FDA Notification in their time alleged in the statement of a claim” in its Opinion.¹² Specifically, Plaintiff claims: “The Complaint, which was filed in 2020, averred Mrs. Bredberg was implanted in 2005. . . This is the entirety of the ‘time alleged’ in the Complaint. For instance, the dates of Mrs. Bredberg’s revisions surgeries in

¹⁰ *Cummings v. Jimmy’s Grille, Inc.*, 2000 WL 1211167, AT *2 (Del Supr. 2000).

¹¹ Superior Court Rule of Civil Procedure 59(e).

¹² Pl.’s Mot. For Reargument, at p. 4 (internal punctuation omitted.)

2005 and 2018 are not listed in the Complaint.”¹³ In essence the plaintiffs argue that the Court improperly considered matters outside of the complaint in reaching its decision, contrary to the standards that apply to a motion to dismiss.¹⁴

“The Complaint generally defines the universe of facts that the trial court may consider in ruling on a Rule 12(b)(6) motion to dismiss.”¹⁵ However, the pleadings and transcript of a case are part of the official court record and are subject to judicial notice, including on a motion to dismiss.¹⁶ The Supreme Court of Delaware has also recognized three specific instances when a trial court may look beyond the complaint: (1) when a document is integral to a claim and incorporated into a complaint; (2) when the document is not being relied upon to prove the truths of its contents; or (3) when the document is an adjudicative fact subject to judicial notice.¹⁷ A pleading in a case is a part of the official court record and the undisputed facts in these pleadings can be considered by the court on a motion to dismiss.

¹³ *Id.*

¹⁴ The Court notes that ordinarily, when facts outside of the complaint are cited as the basis for a motion to dismiss pursuant to Rule 12(b)(6), then the 12(b)(6) motion will be converted into a summary judgment motion under Rule 56 and will be analyzed accordingly. This will normally trigger the discovery process in order to develop a more complete factual record. *See e.g. In re General Motors (Hughes) S'holder Litig.*, 897 A.2d 162, 168 (Del. 2006) (“When [a] trial court considers matters outside of the complaint, a motion to dismiss is usually converted into a motion for summary judgment and the parties are permitted to expand the record.”); *see also Lagrone v. American Mortell Corp.*, 2008 WL 4152677, at *4 (Del. Supr. 2008) (“In determining whether to convert a motion to dismiss to a motion for summary judgment, the court must first consider whether the movant, in fact, has attached or relied upon matters outside the pleadings as contemplated by Superior Court Civil Rule 12(b).”)(internal citations omitted). Given the fact that the dates of Dawnette’s two revision surgeries were within the pleadings and have not been disputed by the Plaintiffs, it is this Court’s view that it was not appropriate to convert the Defendant’s 12(b)(6) motion into a motion for summary judgment. It was not necessary to engage in the often protracted and expensive discovery process to determine the date of Dawnette’s first revision surgery, since this fact was admitted by the Plaintiff in both the text of the Response Brief and the Plaintiff Profile Form.

¹⁵ *In re General Motors*, 897 A2d at 169 (Del. 2006).

¹⁶ *Lagrone v. American Mortell Corp.*, at *4 (“... the pleadings and transcripts are part of the official court record and are subject to judicial notice. As such, they may properly be considered on a motion to dismiss.”)

¹⁷ *In Re Gardner Denver, Inc.*, 2014 WL 715705, at 2 (Del Ch 2014)

While Plaintiffs did not list the 2005 date of Dawnette Bredberg's first revision surgery in the text of the Complaint itself, Plaintiffs *did* list the date of Dawnette's first revision surgery in two other pleadings. First, Plaintiff's listed the date of Dawnette's first revision surgery in their Response Brief to Boston Scientific's Motion to Dismiss. The first page of that document states: "On December 28, 2005, Mrs. Bredberg underwent revision surgery to remove mesh from the Obtryx device that eroded into her vagina."¹⁸

If this was the only reference to this surgery in the pleadings, this Court might be hesitant to consider this fact in the context of a Motion to Dismiss. But this is not the only pleading which references this fact. Plaintiffs also submitted a "Plaintiff Profile Form" as an exhibit to their Response Brief. The Plaintiff Profile Form is a standardized court document which the parties have agreed to file in this case and the companion litigation to this case addressing pelvic mesh devices manufactured by Defendant.¹⁹ This form is akin to the standard Rule 5 Form 30 Interrogatories which are required to be filed with all other types of personal injury actions. Like the Answers to Form 30 Interrogatories, Plaintiffs were required to verify under oath that the information contained in the Profile Form was truthful. The text of the instructions listed on the Profile Form explicitly state: "In completing this Profile

¹⁸ Response, at 1.

¹⁹ See *Shealy v. Boston Scientific Corp.* C.A. No. N21C-01-068 PEL; see also *Hagan v. Boston Scientific Corp.* C.A. No. N20C-10-208 PEL; *Gunter v. Boston Scientific Corp.* C.A. No. N20C-11-023 PEL; *Barnett v. Boston Scientific Corp.*, C.A. No. N20C-12-076 PEL (companion litigation filed in the Superior Court, featuring identical claims to the instant litigation).

Form, you [the Plaintiff] are under oath and must provide information that is true and correct to the best of your knowledge.”²⁰ Section IV of the Profile Form is titled “Removal/Revision Surgery Information” and lists the dates of Dawnette’s two revision surgeries: 12/28/2005 and 10/03/2018.²¹

These two documents – most importantly verified the Plaintiff’s Profile Form – clearly list the date of Dawnette’s first revision surgery in December of 2005, only a few months after her initial implantation surgery. The Court is permitted to take this fact into consideration under the doctrine of judicial notice.²² The Plaintiff’s Response Brief and the accompanying Plaintiff Profile Form represent part of the pleadings, and the Court may consider undisputed facts contained within those documents on a motion to dismiss.²³ It was therefore appropriate for this Court to take the admitted date of Dawnette’s first revision surgery in December of 2005 into account when determining whether the statute of limitations for her personal injury claims and the derivative claim contained in Count IV had expired.

Plaintiffs next argues that under Delaware and Third Circuit precedent, the public Notice issued by the FDA in 2008 was insufficient to begin the running of the statute of limitations for Dawnette’s personal injury claims. This Court, citing the U.S. District Court for the Western District of Pennsylvania’s 2018 decision in

²⁰ Plaintiff Profile Form, at 1.

²¹ Plaintiff Profile Form, at 2.

²² See *Langorne*, 2008 WL 4152677, at fn. 24 (collecting cases in which the Court has considered matters outside the four-corners of the initial complaint in deciding a motion to dismiss).

²³ *Lagrone*, at *4.

*Wallace v. Boston Scientific Corp.*²⁴, has recently denied several motions to dismiss personal injury claims for pelvic mesh devices manufactured by Boston Scientific in companion litigation to this case. In *Hagan, Gunter, Barnett, and Shealy*, Boston Scientific raised similar arguments that the statute of limitations for personal injury claims based on the company's pelvic mesh devices began to run after the FDA issued its public Notice concerning the potential health hazards of such devices in 2008. One key fact differentiates this case from its counterparts: Dawnette Bredberg underwent revision surgery in 2005, while the plaintiffs in the aforementioned cases did not undergo revision surgery prior to 2008. In some cases, the plaintiffs in these additional cases did not undergo their initial pelvic mesh implantation surgery until years after the FDA issued its Notice. Given the fact that Dawnette had undergone revision surgery to correct problems associated with her initial pelvic mesh implantation, the 2008 date of the FDA's public Notice represents the latest possible date upon which her claims could have accrued.²⁵

The Motion for Reargument also maintains that the factual record was not sufficiently developed enough for the Court to determine that the Plaintiffs should

²⁴ 2018 WL 6981220 (U.S. D.C. W.D. Pa., 2018)

²⁵ Plaintiffs' Motion indicates that the FDA's 2008 Notice was included along with the Complaint in this action for the purpose of demonstrating that their claims were non-frivolous, rather than to indicate that Plaintiff had actual or constructive notice of her claims after the FDA issued the Notice in 2008. As Defendant's Response points out, this does not amount to a misapprehension of the facts on the part of the Court. Instead, it represents a different interpretation of the legal significance of the Notice. While it may have been the intention of the Plaintiffs to include the Notice only to demonstrate that their claims were non-frivolous on the merits, the Notice nevertheless is legally sufficient to demonstrate that Plaintiffs' would have been on inquiry notice by 2008 at the latest, in light of Dawnette's initial revision surgery in December of 2005. See *Juran v. Bron Corp.*, 2000 WL 3317131, at *1 (Del. Ch. Oct. 20, 2000) (discussing the Court's "interpretation of the facts" on a motion for reargument and holding that relying on particular facts in the record did not amount to a misapprehension of the facts.) Plaintiff has not introduced any argument that the Court failed to accurately comprehend the substance of the Notice in its Opinion

have been on inquiry notice of Dawnette’s personal injury claims. As Plaintiffs see it, “As there is no record, the Court could not know what efforts were made by Plaintiffs to investigate their injuries, nor could it know any impediments Plaintiffs might have faced in timely and thoroughly conducting that investigation.”²⁶

While it is true that issues related to a Plaintiff’s investigative efforts for a legal claim are often more amenable to determination after the discovery process has taken place, that is not the case here. While the question of inquiry notice is factually-intensive and case-specific, in certain cases where the essential facts cannot be disputed, a case can be dismissed due to expiration of the statute of limitations at the motion to dismiss stage of litigation.²⁷ In many cases, one or two key facts contained in the pleadings may suffice to demonstrate that a plaintiff was on inquiry notice of his or her claims at a date that would preclude a lawsuit due to subsequent expiration of the statute of limitations. In this case, it is clear from the record that Dawnette underwent revision surgery in December of 2005 to correct medical issues that arose after her initial pelvic mesh implantation in April of 2005. A reasonably diligent investigation thereafter would have brought the FDA’s 2008 Notice – which established the appropriate notice that the symptoms which necessitated Dawnette’s first revision surgery in December of 2005 were potentially

²⁶ Mot. For Reargument at 6.

²⁷ See *In re Dean Witter P’ship Litig.*, 1998 WL 442456, at *9 (Del. Ch. July 17, 1998); *Young & McPherson Funeral Home, Inc. v. Butler’s Home Improvement LLC*, 2015 WL 4656486, at *2 (Del. Super. Ct. Aug. 6, 2015) (courts “must...determine when the plaintiff was on inquiry notice of a claim based on the [complaint’s] allegations” for motion to dismiss).

related to her initial Obtryx implantation – to their attention after it was issued by the FDA.

CONCLUSION

For the reasons stated above, the Court is not persuaded that it misunderstood the key facts relevant to granting Boston Scientific’s Motion to Dismiss with respect to Dawnette Bredberg’s personal injury claims or that it misapplied the law with respect to those facts. Accordingly, Plaintiff has not stated a basis to reconsider the decision contained in this Court’s June 2, 2020 decision, and Plaintiff’s Motion for Reargument is **DENIED**.

IT IS SO ORDERED.

/s/ Francis J. Jones, Jr.
Francis J. Jones, Jr., Judge

cc: File&ServeXpress